UNITED STATES PATENT AND TRADEMARK OFFICE

C1C

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,661	02/04/2004	Xiaojun Han	CT 2662 DIV4	3536

23914 7590 11/25/2005

STEPHEN B. DAVIS
BRISTOL-MYERS SQUIBB COMPANY
PATENT DEPARTMENT
P O BOX 4000
PRINCETON, NJ 08543-4000

EXAMINER	
ANDERSON, REBECCA L	
ART UNIT	**PAPER NUMBER**
1626	

DATE MAILED: 11/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/771,661	HAN ET AL.	
	Examiner	Art Unit	
	Rebecca L. Anderson	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☒ Claim(s) *17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *29 April 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-17 are currently pending in the instant application. Claims 1-17 are rejected and claim 17 is also objected.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-17, and the further election of example 237 in the reply filed on 18 August 2005 is acknowledged. The traversal is on the ground(s) that no further amendments to the scope of claims 1-17 is required for the restriction requirement. The examiner agrees that the entire scope of the product claims 1-17 will be searched and examined in the instant application as the elected invention for search and examination.

The requirement is still deemed proper.

Applicants' have cancelled claim 18 directed to methods of treatment and pursuant to MPEP 809.04, regarding rejoinder of claims, reserve the right to reintroduce method of use claims, which include all the limitations of product claims, for rejoinder when the product claims are deemed to be allowable.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. [1] as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional

application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/264,570 fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Specifically, Provisional Application No. 60,264,570 does not provide support or enablement for compounds of the formula (I) wherein, for example, R1 is cyano, or halo; and/or R2 is D'-D"(R3)(R4); and/or R3 and R4 are C1-6haloalkyl, -C1-6hydroxyalkyl, -C1-4alkylene-O-C1-4alkyl, -C1-3alkylene-C1-6-thioalkyl, -C2-6alkylidene-(C1-4alkoxy)2, C3-7cycloalkyl; and/or wherein said aryl of –C1-6alkylene-aryl of R3 and R4 is optionally substituted; and/or when R3 and R4 together with the nitrogen to which they are attached form a five or six-membered heterocycle, said heterocycle is optionally substituted with one or more aryl, -C1-4alkylene-aryl, pyridyl; and/or V is 2-pyridyl. There is no disclosure or description found anywhere in Provisional Application No. 60,264,570 for the above mentioned compounds of the formula (I).

Accordingly, claims 1-17 are not entitled to the benefit of the prior application as claims 1-17 all include subject matter not supported by Provisional Application No. 60,264,570.

Claim Objections

Claim 17 is objected to because of the following informalities: Claim 17 lists the compounds of [8-(2-Chloro-4,6-dimethyl-phenyl)-2-methyl-8H-1,3a,7,8-tetraaza-cyclopenta[a]inden-3-ylmethyl]-phenethyl-propyl-amine and [8-(2-Chloro-4,6-dimethyl-phenyl)-2-methyl-8H-1,3a,7,8-tetraaza-cyclopenta[a]inden-3-ylmethyl]-ethyl-phenethyl-amine twice in the claim. Claim 17 should only list the chemical names once in the claim. Appropriate correction is required. It is suggested that applicants' delete the second instance of each of these chemical names from claim 17.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim 1 defines E1 and E3 as "E1 and E3 together form N(CH)3". Claim 1 also lists as an optional substituent on E1 and E3, "N(C1-4alkyl)2". Claims 14-16 also define E1 and E3 as together forming N(CH)3. It is unclear what applicant is claiming with the definition of E1 and E3 as forming N(CH)3. While applicants' elected compound of the formula 237 has E1 and E3 together forming =N-CH=CH-CH=, along with examples 210-282, it is unclear how E1 and E3 together forming N(CH)3 particularly points out and distinctly claims the subject matter which applicant regards as the invention as this would require N(CH)3 to be read as a chain. The reasoning for the consideration of indefinite is that as in Organic Chemistry/John

McMurry-fifth ed., page 62, condensed structures which utilize parentheses, such as CH(CH3)2 are understood to read where the atoms in the parentheses are both attached to the atom outside the parentheses, such as CH-CH3. Furthermore, applicants' own optional substituents on E1 and E3, include N(C1-4alkyl)2 which is understood to read that each C1-4alkyl is directly attached to the nitrogen as N-(C1-4alkyl), i.e. it is not read as a chain N-C1-4alkyl-C1-4alkyl. Therefore, it is unclear whether the parentheses should be read as a chain or as members inside the parentheses all being directly attached to the outside atom. While an applicant is his own lexicographer, applicant may not distort art-recognized terms. Ex parte Klager, 132 USPQ 203 (POBA 1959). Therefore, it is suggested that applicant delete the definition of E1 and E3 as N(CH)3 and insert in its place, =N-CH=CH-CH= which is supported by pages 213-247 of the instant specification and by examples 210-282 to overcome this rejection.

Claim Rejections - 35 USC § 102

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

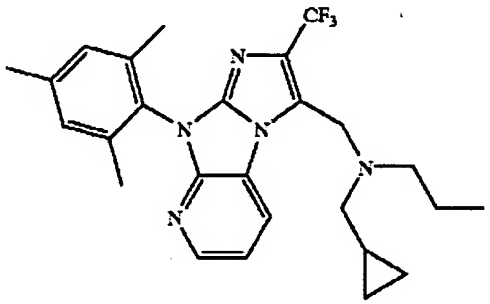
Claims 1, 2, 4, 5, 7 and 10-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Dubowchik et al., US Patent No. 6,888.004.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome

either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Dubowchik et al., discloses the compounds, for example, of examples 211, 214, 215, 217, 218, 219, 220, 223, 228, 229, 230, 231, 233, 235, 236, 237, 238, 239, 240, 241, 242, 243, 244, 245, 246, 247, 248, 249, 250, 251, 252, 253, 254, 255, 257, 258, 259, 260, 261, 262, 263, 264, 265, 266, 268, 269, 270, 274, 276, 277, 278, 279 and 280 which anticipate applicants' instant claimed invention. Example 211 of Dubowchik et al. is on column 145 and has the following formula:

EXAMPLE 211

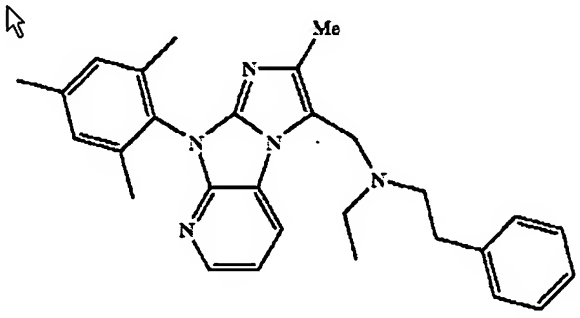


Cyclopropylmethyl-propyl-[2-trifluoromethyl-8-(2,4,6-trimethyl-phenyl)-8H-1,3a,7,8-tetraaza-cyclopenta[α]inden-3-ylmethyl]-amine, scheme 2: (H)

, which corresponds to applicants instant invention wherein: R1 is C1-6haloalkyl; R2 is CH2NR3R4; one of R3 and R4 is C1-6alkyl and the other is C1-6alkylene-C3-7cycloalkyl; X is C; Y is C; A is the formula found on page 3 of the most recent claims listing; X1 is N, Y1 is N, G is the formula found on page 4 of the most recent claims listing; Y2 is CE1; J is a bond; Z1 is CE3; E1

and E3 together form N(CH)3; Z is N-V; and V is phenyl substituted with three C1-4alkyl. Example 237 of Dubowchik et al. is found on column 154 and has the formula:

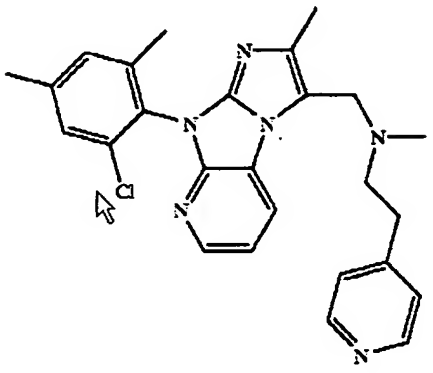
EXAMPLE 237



Ethyl-[2-methyl-8-(2,4,6-trimethyl-phenyl)-8H-1,3a,7,8-tetraaza-cyclopenta[α]inden-3-ylmethyl]-phenethyl-amine, scheme 2: (H)

, which corresponds to applicants instant invention wherein: R1 is C1-6alkyl; R2 is CH2NR3R4; one of R3 and R4 is C1-6alkyl and the other is C1-6alkylene-aryl; X is C; Y is C; A is the formula found on page 3 of the most recent claims listing; X1 is N, Y1 is N, G is the formula found on page 4 of the most recent claims listing; Y2 is CE1; J is a bond; Z1 is CE3; E1 and E3 together form N(CH)3; Z is N-V; and V is phenyl substituted with three C1-4alkyl. Example 280 of Dubowchik et al. is found on column 168 and has the following formula:

EXAMPLE 280



[8-(2-Chloro-4,6-dimethyl-phenyl)-2-methyl-8H-1,3a,7,8-tetraaza-cyclopenta[α]inden-3-ylmethyl]-methyl-(2-pyridin-4-yl-ethyl)-amine, scheme 2: (H)

, which corresponds to applicants instant invention wherein R1 is C1-6alkyl; R2 is CH2NR3R4; one of R3 and R4 is C1-6alkyl and the other is C1-6alkylene-heterocycle; X is C; Y is C; A is the formula found on page 3 of the most recent claims listing; X1 is N, Y1 is N, G is the formula found on page 4 of the most recent claims listing; Y2 is CE1; J is a bond; Z1 is CE3; E1 and E3 together form N(CH)3; Z is N-V; and V is phenyl substituted with two C1-4alkyl groups and a halogen.

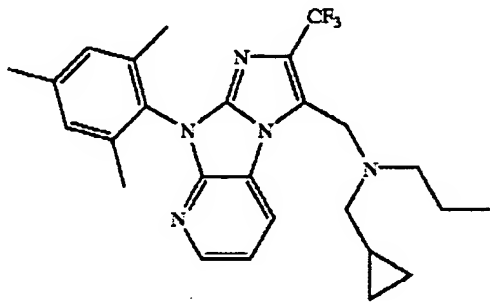
Claims 1, 2, 4, 5, 7 and 10-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Vrudhula et al., US Pre-Grant Publication 2004/0254382.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Vrudhula et al., discloses the compounds, for example, of examples 211, 214, 215, 217, 218, 219, 220, 223, 228, 229, 230, 231, 233, 235, 236, 237, 238, 239, 240, 241, 242, 243, 244, 245, 246, 247, 248, 249, 250, 251, 252, 253, 254, 255, 257, 258, 259, 260, 261, 262, 263, 264, 265, 266, 268, 269, 270, 274, 276, 277, 278, 279 and 280 which anticipate applicants' instant claimed invention. Example 211 of Vrudhula et al. is on page 83 and has the following formula:

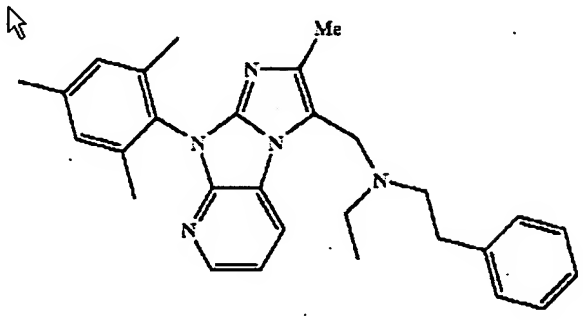
EXAMPLE 211



Cyclopropylmethyl-propyl-[2-trifluoromethyl-8-(2,4,6-trimethyl-phenyl)-8H-1,3a,7,8-tetraaza-cyclopenta[α]inden-3-ylmethyl]-amine, scheme 2: (H)

, which corresponds to applicants instant invention wherein: R1 is C1-6haloalkyl; R2 is CH2NR3R4; one of R3 and R4 is C1-6alkyl and the other is C1-6alkylene-C3-7cycloalkyl; X is C; Y is C; A is the formula found on page 3 of the most recent claims listing; X1 is N, Y1 is N, G is the formula found on page 4 of the most recent claims listing; Y2 is CE1; J is a bond; Z1 is CE3; E1 and E3 together form N(CH)3; Z is N-V; and V is phenyl substituted with three C1-4alkyl. Example 237 of Vrudhula et al. is found on page 88 and has the formula:

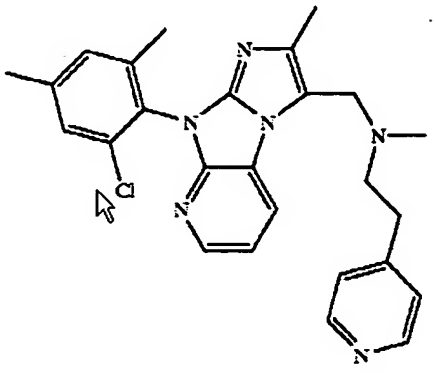
EXAMPLE 237



Ethyl-[2-methyl-8-(2,4,6-trimethyl-phenyl)-8H-1,3a,7,8-tetraaza-cyclopenta[α]inden-3-ylmethyl]-phenethyl-amine, scheme 2: (H)

, which corresponds to applicants instant invention wherein: R1 is C1-6alkyl; R2 is CH2NR3R4; one of R3 and R4 is C1-6alkyl and the other is C1-6alkylene-aryl; X is C; Y is C; A is the formula found on page 3 of the most recent claims listing; X1 is N, Y1 is N, G is the formula found on page 4 of the most recent claims listing; Y2 is CE1; J is a bond; Z1 is CE3; E1 and E3 together form N(CH)3; Z is N-V; and V is phenyl substituted with three C1-4alkyl. Example 280 of Vrudhula et al.. is found on page 96 and has the following formula:

EXAMPLE 280



[8-(2-Chloro-4,6-dimethyl-phenyl)-2-methyl-8H-1,3a,7,8-tetraaza-cyclopenta[α]inden-3-ylmethyl]-methyl-(2-pyridin-4-yl-ethyl)-amine, scheme 2: (H)

, which corresponds to applicants instant invention wherein R1 is C1-6alkyl; R2 is CH2NR3R4; one of R3 and R4 is C1-6alkyl and the other is C1-6alkylene-heterocycle; X is C; Y is C; A is the formula found on page 3 of the most recent claims listing; X1 is N, Y1 is N, G is the formula found on page 4 of the most recent claims listing; Y2 is CE1; J is a bond; Z1 is CE3; E1 and E3 together form N(CH)3; Z is N-V; and V is phenyl substituted with two C1-4alkyl groups and a halogen.

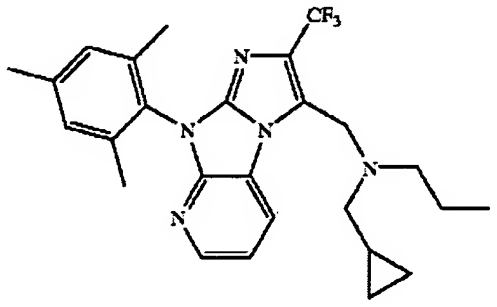
Claims 1, 2, 4, 5, 7 and 10-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Vrudhula et al., US Pre-Grant Publication 2004/00225001.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Vrudhula et al., discloses the compounds, for example, of examples 211, 214, 215, 217, 218, 219, 220, 223, 228, 229, 230, 231, 233, 235, 236, 237, 238, 239, 240, 241, 242, 243, 244, 245, 246, 247, 248, 249, 250, 251, 252, 253, 254, 255, 257, 258, 259, 260, 261, 262, 263, 264, 265, 266, 268, 269, 270, 274, 276, 277, 278, 279 and 280 which anticipate applicants' instant claimed invention. Example 211 of Vrudhula et al. is on page 79 and has the following formula:

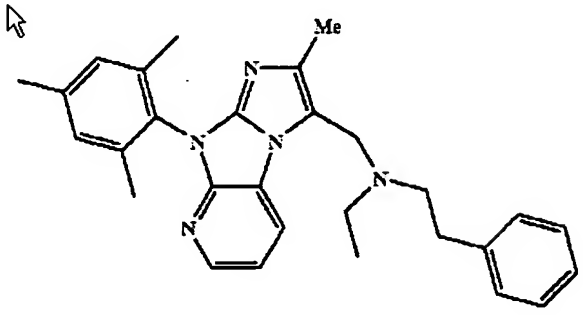
EXAMPLE 211



Cyclopropylmethyl-propyl-[2-trifluoromethyl-8-(2,4,6-trimethyl-phenyl)-8H-1,3a,7,8-tetraaza-cyclopenta[α] inden-3-ylmethyl]-amine, scheme 2: (H)

, which corresponds to applicants instant invention wherein: R1 is C1-6haloalkyl; R2 is CH2NR3R4; one of R3 and R4 is C1-6alkyl and the other is C1-6alkylene-C3-7cycloalkyl; X is C; Y is C; A is the formula found on page 3 of the most recent claims listing; X1 is N, Y1 is N, G is the formula found on page 4 of the most recent claims listing; Y2 is CE1; J is a bond; Z1 is CE3; E1 and E3 together form N(CH)3; Z is N-V; and V is phenyl substituted with three C1-4alkyl. Example 237 of Vrudhula et al. is found on page 83 and has the formula:

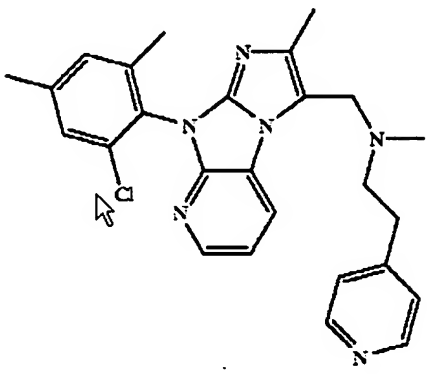
EXAMPLE 237



Ethyl-[2-methyl-8-(2,4,6-trimethyl-phenyl)-8H-1,3a,7,8-tetraaza-cyclopenta[α]inden-3-ylmethyl]-phenethyl-amine, scheme 2: (H)

, which corresponds to applicants instant invention wherein: R1 is C1-6alkyl; R2 is CH2NR3R4; one of R3 and R4 is C1-6alkyl and the other is C1-6alkylene-aryl; X is C; Y is C; A is the formula found on page 3 of the most recent claims listing; X1 is N, Y1 is N, G is the formula found on page 4 of the most recent claims listing; Y2 is CE1; J is a bond; Z1 is CE3; E1 and E3 together form N(CH)3; Z is N-V; and V is phenyl substituted with three C1-4alkyl. Example 280 of Vrudhula et al.. is found on page 91 and has the following formula:

EXAMPLE 280



[8-(2-Chloro-4,6-dimethyl-phenyl)-2-methyl-8H-1,3a,7,8-tetraaza-cyclopenta[α]inden-3-ylmethyl]-methyl-(2-pyridin-4-yl-ethyl)-amine, scheme 2: (H)

, which corresponds to applicants instant invention wherein R1 is C1-6alkyl; R2 is CH2NR3R4; one of R3 and R4 is C1-6alkyl and the other is C1-6alkylene-heterocycle; X is C; Y is C; A is the formula found on page 3 of the most recent claims listing; X1 is N, Y1 is N, G is the formula found on page 4 of the most recent claims listing; Y2 is CE1; J is a bond; Z1 is CE3; E1 and E3 together form N(CH)3; Z is N-V; and V is phenyl substituted with two C1-4alkyl groups and a halogen.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 6 is rejected under 35 U.S.C. 103(a) as being obvious over US Patent No. 6,888,004.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed

in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Applicants instant claim 6 is drawn to a compound according to claim 1 wherein R2 is C(D)NR3R4 and D is O.

Determining the scope and contents of the prior art

US Patent No. 6,888,004 discloses the antagonist of the CRF receptor of the formula (I), column 2, wherein R2 can be C(D)NR3R4, D'-D"(R3)(R4) or CH2NR3R4 and D is O or S, which generically encompasses applicants' instantly claimed invention. Column 4 discloses a preferred embodiment of the disclosed invention wherein R2 is C(D)NR3R4 and D is O, lines 32-35. Columns 7 and 8 disclose further preferred embodiments of the invention wherein R2 is C(O)NR3R4. Column 121, discloses the compound of example 142 wherein R2 is C(O)NR3R4 wherein R3 is C1-6alkylene-C3-7cycloalkyl and R4 is C1-6 alkyl, which only differs from applicants instantly claimed invention by E1 and E3 forming a benzene ring. However, a preference is also shown for E1 and E3 forming a pyridine ring as seen in examples 211, 214, 215, 217, 218, 219, 220, 223, 228, 229, 230, 231, 233, 235, 236, 237, 238, 239, 240, 241, 242, 243, 244, 245, 246, 247, 248, 249, 250, 251, 252, 253, 254, 255, 257, 258, 259, 260, 261,

262, 263, 264, 265, 266, 268, 269, 270, 274, 276, 277, 278, 279 and 280. Therefore, US Patent No. 6,888.004 discloses the compound of the formula (I) which generically encompasses applicants' instant claimed invention, provides preferences towards R2 as C(O)NR3R4 by preferred embodiments and prepares example compounds wherein R2 is C(O)NR3R4 and provides preferences towards E1 and E3 forming a pyridine ring in varying examples.

Ascertaining the differences between the prior art and the claims at issue

The difference between the prior art and the claims at issue is that the prior art generically encompasses applicants' instantly claimed invention and provides preferences towards applicants' instantly claimed invention wherein R2 is C(O)NR3R4 but does not provide a specific example wherein R2 is C(O)NR3R4 and E1 and E2 form a pyridine ring.

Resolving the level of ordinary skill in the pertinent art

However, it would have been obvious to one of ordinary skill in the art at the time of the invention to prepare applicants' instantly claimed invention wherein R2 is C(O)NR3R4 when faced with the prior art of US Patent No. 6,888,004 which generically encompasses applicants' instantly claimed invention and provides preferences towards R2 as C(O)NR3R4. The motivation would be to prepare additional compounds for the treatment of depression with a high expectation of success.

Claim 6 is rejected under 35 U.S.C. 103(a) as being obvious over US PG Pub 2004/0254382.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Applicants instant claim 6 is drawn to a compound according to claim 1 wherein R2 is C(D)NR3R4 and D is O.

Determining the scope and contents of the prior art

US PG Pub 2004/0254382 discloses the antagonist of the CRF receptor of the formula (I), page 1, wherein R2 can be C(D)NR3R4, D'-D"(R3)(R4) or CH2NR3R4 and D is O or S, which generically encompasses applicants' instantly claimed invention. Page 3 discloses a preferred embodiment of the disclosed invention wherein R2 is C(D)NR3R4 and D is O. Page 4 discloses further preferred embodiments of the

invention wherein R2 is C(O)NR3R4. Page 69, discloses the compound of example 142 wherein R2 is C(O)NR3R4 wherein R3 is C1-6alkylene-C3-7cycloalkyl and R4 is C1-6 alkyl, which only differs from applicants instantly claimed invention by E1 and E3 forming a benzene ring. However, a preference is also shown for E1 and E3 forming a pyridine ring as seen in examples 211, 214, 215, 217, 218, 219, 220, 223, 228, 229, 230, 231, 233, 235, 236, 237, 238, 239, 240, 241, 242, 243, 244, 245, 246, 247, 248, 249, 250, 251, 252, 253, 254, 255, 257, 258, 259, 260, 261, 262, 263, 264, 265, 266, 268, 269, 270, 274, 276, 277, 278, 279 and 280. Therefore, US PG Pub 2004/0254382 discloses the compound of the formula (I) which generically encompasses applicants' instant claimed invention, provides preferences towards R2 as C(O)NR3R4 by preferred embodiments and prepares example compounds wherein R2 is C(O)NR3R4 and provides preferences towards E1 and E3 forming a pyridine ring in varying examples.

Ascertaining the differences between the prior art and the claims at issue

The difference between the prior art and the claims at issue is that the prior art generically encompasses applicants' instantly claimed invention and provides preferences towards applicants' instantly claimed invention wherein R2 is C(O)NR3R4 but does not provide a specific example wherein R2 is C(O)NR3R4 and E1 and E2 form a pyridine ring.

Resolving the level of ordinary skill in the pertinent art

However, it would have been obvious to one of ordinary skill in the art at the time of the invention to prepare applicants' instantly claimed invention wherein R2 is C(O)NR3R4 when faced with the prior art of US PG Pub 2004/0254382 which

generically encompasses applicants' instantly claimed invention and provides preferences towards R2 as C(O)NR3R4. The motivation would be to prepare additional compounds for the treatment of depression with a high expectation of success.

Claim 6 is rejected under 35 U.S.C. 103(a) as being obvious over US PG Pub 2004/0225001.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Applicants instant claim 6 is drawn to a compound according to claim 1 wherein R2 is C(D)NR3R4 and D is O.

Determining the scope and contents of the prior art

US PG Pub 2004/0225001 discloses the antagonist of the CRF receptor of the formula (I), page 1, wherein R2 can be C(D)NR3R4, D'-D"(R3)(R4) or CH2NR3R4 and D is O or S, which generically encompasses applicants' instantly claimed invention. Page 3 discloses a preferred embodiment of the disclosed invention wherein R2 is C(D)NR3R4 and D is O. Page 4 discloses further preferred embodiments of the invention wherein R2 is C(O)NR3R4. Page 66, discloses the compound of example 142 wherein R2 is C(O)NR3R4 wherein R3 is C1-6alkylene-C3-7cycloalkyl and R4 is C1-6 alkyl, which only differs from applicants instantly claimed invention by E1 and E3 forming a benzene ring. However, a preference is also shown for E1 and E3 forming a pyridine ring as seen in examples 211, 214, 215, 217, 218, 219, 220, 223, 228, 229, 230, 231, 233, 235, 236, 237, 238, 239, 240, 241, 242, 243, 244, 245, 246, 247, 248, 249, 250, 251, 252, 253, 254, 255, 257, 258, 259, 260, 261, 262, 263, 264, 265, 266, 268, 269, 270, 274, 276, 277, 278, 279 and 280. Therefore, US PG Pub 2004/0254382 discloses the compound of the formula (I) which generically encompasses applicants' instant claimed invention, provides preferences towards R2 as C(O)NR3R4 by preferred embodiments and prepares example compounds wherein R2 is C(O)NR3R4 and provides preferences towards E1 and E3 forming a pyridine ring in varying examples.

Ascertaining the differences between the prior art and the claims at issue

The difference between the prior art and the claims at issue is that the prior art generically encompasses applicants' instantly claimed invention and provides preferences towards applicants' instantly claimed invention wherein R2 is C(O)NR3R4

but does not provide a specific example wherein R2 is C(O)NR3R4 and E1 and E2 form a pyridine ring.

Resolving the level of ordinary skill in the pertinent art

However, it would have been obvious to one of ordinary skill in the art at the time of the invention to prepare applicants' instantly claimed invention wherein R2 is C(O)NR3R4 when faced with the prior art of US PG Pub 2004/0225001 which generically encompasses applicants' instantly claimed invention and provides preferences towards R2 as C(O)NR3R4. The motivation would be to prepare additional compounds for the treatment of depression with a high expectation of success.

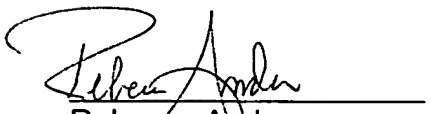
Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday 5:30AM to 2:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



November 10, 2005

Rebecca Anderson
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600